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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,330	01/23/2004	Michael P. Cooke	P1097US10	5772

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EXAMINER	
JUEDES, AMY E	
ART UNIT	**PAPER NUMBER**
1644	

NOTIFICATION DATE	DELIVERY MODE
06/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPLegal@gnf.org
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Office Action Summary	Application No.	Applicant(s)	
	10/764,330	COOKE ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12 and 14-39* is/are pending in the application.

4a) Of the above claim(s) *17-27 and 34-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,14-16 and 28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, remarks, and declaration of Inventor Cooke, filed 3/14/07, are acknowledged.

Claims 12 and 14 have been amended.
Claims 1-11 and 13 have been cancelled.
Claims 28-38 have been added.
Claims 12 and 14-38 are pending.

2. Claims 17-27 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Additionally, claims 36-38 are withdrawn from consideration, since they are drawn to methods comprising screening and administering an agent to a subject, which are part of non-elected group III. Furthermore, newly submitted claim 34-35 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 34-35 are directed to a method for identifying an agent that modulates B cell development, while the claims under examination are directed to identifying an agent that inhibits T lymphocyte differentiation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 34-35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 12, 14-16, and 28-33, as they read on a method of identifying an agent that inhibits T lymphocyte differentiation, are being acted upon.

3. In view of Applicant's amendment, the rejection of the claims under 35 U.S.C. 112 second paragraph, as outline in sections C)-D) are withdrawn.

4. The rejections of the claims under 35 U.S.C. 112 first paragraph are withdrawn in view of Applicant's amendment. However, Applicant's arguments relevant to the new grounds of rejection will be addressed below.

5. The rejection of the claims under 35 U.S.C. 102 as being anticipated by Chang et al. is moot, in view of Applicant's

cancellation of the claims.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 14-16 stand rejected, and claims 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As set forth previously, A) The term "modulates" is a relative term that renders claims 1, 2, 4, 9, 11-12, 14, and 16 indefinite. The specification on page 9 states that the term "modulate" with respect to IP3K refers to a change in the cellular level or other biological activities of IP3K. However, this definition is not adequate to define the metes and bounds of term "modulates". For example, it is not at all clear what "other biological activities" might encompass. Additionally, it is not clear what direction, degree, or type of modulation is required. For example "modulates" might encompass an increase or a decrease in activity. Additionally, modulate might indicate that an activity is turned on or off, or could also indicate an upregulation or downregulation of a particular activity to an unspecified degree. In addition, said modulation could be intermittent, or constant. Therefore, even taking into account the definition provided by the instant specification, the term modulates is so vague that the metes and bounds of the claims cannot be established. Furthermore, it is noted that no definition is provided as to the metes and bounds of "modulating" T cell lymphocyte development or function, as recited in claim 1.

B) Claims 14-15 are indefinite in the recitation of a method wherein the modulating agent inhibits kinase activity. The claims do not actually recite an active method step, and it is unclear how the inhibition of kinase activity relates to independent claim 1, which comprises identifying an IP3K modulating agent. Are the claims intended to mean that the cellular activity being assaying for in claim 1 is kinase activity?

Applicant's arguments filed 3/14/07 have been fully considered, but they are not persuasive.

Regarding A), Applicant argues that the amendment to recite screening for agents that inhibit T cell differentiation obviates the rejection.

However, independent claim 12, as well as dependent claims 14, 16, 30, and 32 still recite "modulating" agents, and independent claim 12 still recites identifying an agent that "modulates" inhibits T lymphocyte differentiation in lines 8-9. Thus, the scope of the claims is not clear.

Regarding B), Applicant argues that the amended claims are clear and definite since they recite the active steps of

screening agents and testing said agents.

However, it is still not clear if the "cellular activity" being assayed for in independent claim 12 is the kinase activity recited in claims 14-15. Or are the claims intended to encompass identifying an agent that inhibits a cellular activity in addition to the kinase activity?

7. Claims 12 and 14-16 stand rejected, and claims 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

As set forth previously, The claims are incomplete for omitting essential steps. While all of the technical details need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The instant claims are drawn to a method comprising assaying a cellular activity of IP3K in the presence of a test compound to identify a modulating agent. However, the instant claims do not specify how the modulating is to be identified. For example, is the test compound identified as a modulating agent if it exhibits a particular effect on the IP3K, or is the modulatory agent some other component of the assay?

Applicant's arguments filed 3/14/07 have been fully considered, but they are not persuasive.

Applicant argues that the amended claims are clear and definite since they recite the active steps of screening agents and testing said agents.

The instant claims still recite assaying a cellular activity of IP3KB in the presence of a test agent, followed by identifying a modulating agent. It is not clear how the modulating agent is to be identified in the absence of some type of active method step involving said modulating agent.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 12 and 14-15 stand rejected, and claims 28-29 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by da Silva et al., 1994, as evidenced by Wen et al., 2004.

As set forth previously, da Silva et al. teach a method comprising assaying the kinase ability of inositol 1,4,5-triphosphate 3-kinase (i.e. IP3K) in the present of adriamycin (i.e. a test compound), see page 12523, in particular). Furthermore, da Silva et al. specifically teach assaying for the catalysis of IP3 to IP4 (see page 12523 and Fig. 5 in particular). Furthermore, since one activity of IP3KB is converting IP3 to IP4 (see Wen et al., page 5604), da Silva et al. have assayed for a cellular activity of IP3KB (including accession No. NP_002212). da Silva et al. further teach that adriamycin is an agent that inhibits T cell proliferation (i.e. modulates T cell function/differentiation), see Fig. 3 in particular).

Applicant's arguments filed 3/14/07 have been fully considered, but they are not persuasive.

Applicant argues that da Silva et al. do not teach IP3KB have the specific amino acid sequences of the claims. Applicant has further submitted a declaration by Inventor Cooke as evidence of the fact that adriamycin does not inhibit IP3KB.

The declaration of Inventor Cooke provides experimental evidence demonstrating that adriamyicin does not inhibit IP3KB. However, the instant claims are not limited to assaying for or identifying an agent that inhibits IP3KB. Rather, the claims recite assaying an agent that inhibits a *cellular activity* of IP3KB. da Silva et al. teach assaying for the catalysis of IP3 to IP4, which is a cellular activity of IP3KB, including the IP3KB of accession No. NP_002212.

10. The following are new grounds of rejection necessitated by Applicant's amendment.

11. Claims 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30 and 32 are indefinite in the recitation of a modulating agent that decreases cellular levels of IP3KB, or inhibits expression of the gene encoding IP3KB. It is unclear how the ability to inhibit gene expression is related to the method of independent claim 12. Are the claims intended to mean that the identified modulatory agents that inhibit a cellular activity, are also capable of inhibiting IK3KB gene expression? Or are the claim intended to mean that the cellular activity being assaying for in claim 12 is the cellular level of IP3KB? If the latter, it is unclear how the cellular level of IP3KB gene can be considered a "cellular activity" of IP3KB.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 12, 14-16, and 28-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is insufficient written description to show that Applicant was in possession of the genus of molecules encompassed by "functional derivatives having 90% sequence identity" with IP3KB or sequences "90% identical" with IP3KB.

The instant claims encompass employing a genus of "functional derivatives" of IKB3 having "90% sequence identity" to a sequence encoding IKB3. Thus, the claims might encompass using proteins with a large number of amino acid substitutions, deletions, or additions to the amino acid sequences of any IKB3 protein. Furthermore, the claims might encompass said protein comprising additional chemical modifications (i.e. "derivatives"). Furthermore, the claims do not specify what "function" is required of the derivatives. For example, any protein might function as an antigen to induce an antibody response. Therefore, the claims might encompass derivatives that "function" to induce antibodies. In contrast to the broad genus of structurally and functionally different "derivatives" encompassed by the claims, the instant specification does not disclosed a single species of "functional derivative".

Likewise, the claims encompass employing IP3KB proteins that are "90 identical" to the amino acid sequences recited in claim 28, or are encoded by a nucleotide sequence having "90% identity" to the nucleotide sequences recited in claim 29. Thus, the claims might encompass using proteins with a large number of amino acid substitutions, deletions, or additions to the amino acid sequences of claims 28 and 29. These proteins would all be structurally different due to their unique amino acid sequences. Furthermore, the claims do not recite any functional limitations

of the "90% identical" proteins. Therefore, the instant claims might encompass using structurally different proteins with different cellular activities (i.e. functions). Additionally, Applicant has not disclosed a single species of protein "90% identical" to a amino acid or nucleotide sequence of IK3B. Thus, one of skill in the art would conclude that the specification fails to provide adequate written description to demonstrate that Applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F. 3d 1559, 43, USPQ2d 1398.

14. Claims 12, 14-16, and 28-33 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A method for identifying an agent that "inhibits" T lymphocyte differentiation or a method comprising testing for the ability to "inhibit" T lymphocyte development or function (Claim 12, and dependant claims 14-16 and 28-33).

Applicant has not cited any support for the new limitations in the specification. A review of the specification fails to reveal support for the new limitations.

At page 2, the specification discloses a method of identifying agents that modulate T lymphocytes comprising testing for the ability to modulate T cell differentiation. However, the specification does not disclose testing for the ability to "inhibit" T lymphocyte development or function. While original claim 16 recited testing for the ability to inhibit CD4+CD8+ T cell development into CD4+ or CD8+ cells, this does not provide adequate support for the more generic method now claimed, which encompasses testing for the ability to inhibit any T lymphocyte development or function.

15. No claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS**

ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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5/29/07

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